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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MITRA, RITA	

ART UNIT	PAPER NUMBER
1653	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/556,246	JAY, GREGORY D.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *7-9,14,15,30-39 and 42-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,10-13,16-29,40 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

Applicants' election without traverse of Group I, claims 1-29, 40 and 41 in paper #8, filed on March 4, 2002 is acknowledged. However the response to restriction requirement is incomplete because there is no indication on the SEQ ID selection requirement (see office action dated October 2. 2001). Examiner called the Attorney on April 25, 2002 and the Attorney selected SEQ ID NO: 1. Since claims 7, 8, 9, 14 and 15 do not read on SEQ ID NO: 1, the Attorney asked the Examiner to hold the claims 7, 8, 9, 14 and 15 as non-elected claims. Therefore, claims 7-9, 14, 15, 30-39 and 42-54 are withdrawn under 37 C. F. R. 1.142 (b) from further consideration by the Examiner, as being drawn to a non-elected invention. Therefore, claims 1-6, 10-13, 16-29, 40 and 41 are pending and are under consideration in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 10-13, 16-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a tribonectin consisting of SEQ ID NO: 1, having at least one O-linked lubricating moiety; does not reasonably provide enablement for any tribonectin that comprises a polypeptide that comprises an amino acid sequence of a spliced variant or a fragment sequence of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are directed to a tribonectin having at least one O-linked lubricating moiety (claims 1, 2), wherein said tribonectin comprises spliced variants of SEQ ID NO: 1 (claims 1-6, 28, 29). The tribonectin is characterized as reducing the coefficient of friction between bearing surfaces (claims 10-12), wherein at least 10% or 40% of said tribonectin is glycosylated (claims 16, 17). The claims recite a tribonectin comprising an amino acid sequence of which is 50% identical to residues 200-1140, or 200-1167, or 200-1212, or 200-1263, inclusive, of SEQ ID NO: 1 (claims 20, 22, 24, 26), or comprising an amino acid sequence residues 200-1140, or 200-1167, or 200-1212, or 200-1263, inclusive, of SEQ ID NO: 1 (claims 21, 23, 25, 27). Claims 40 and 41 are directed to a composition comprising a tribonectin, wherein said composition is suitable for the inhibition of tissue adhesion formation.

The specification, however, only discloses cursory conclusions (see page 4-5, 10), without data to support the findings, which has listed the alternatively spliced variants of MSF (Table 3) and also states that a recombinantly or chemically-produced polypeptide containing at least exon 6 (but not exons 1 or 3) of MSF is useful to prevent and/or treat osteoarthritic disease. However, the specification fails to describe the specific structure (except amino acid sequences) and function of these variants. The specification indicates at page 4 that a tribonectin may contain a polypeptide, that comprises the amino acid sequences of residues 200-1140, or 200-1167, or 200-1212, or 200-1263, inclusive, of SEQ ID NO: 1 (claims 21, 23, 25, 27) or the amino acid sequence of which is 50% identical to residues 200-1140, or 200-1167, or 200-1212, or 200-1263, inclusive, of SEQ ID NO: 1, for examples (claims 20, 22, 24, 26). There are no indicia that the present application enables the full scope in view of the tribonectin that comprises the polypeptide sequence set forth in SEQ ID NO: 1 and a fragment thereof as discussed in the following stated rejection. The present application provides no indicia and no teaching/guidance as to how the full scope of the claims is encompassed.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include: 1) the nature of the invention; 2) the breadth of the claims; 3) the predictability or unpredictability of the art; 4) the amount of direction or guidance

presented; 5) the presence or absence of working examples; 6) the quantity of experimentation necessary; 7) the state of the prior art; and, 8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

1) the nature of the invention:

The nature of the invention is defined by the claims, which include a tribonectin (of any sequence) comprising at least one O-linked lubricating moiety, wherein the said tribonectin comprises within its scope a polypeptide, the amino acids sequence of which is set forth in SEQ ID NO: 1. The scope of the claims includes spliced variants and fragments of polypeptide. However the specification does not provide the information on the structure (except for the amino acid sequence of the spliced variants) and function of the claimed variants and fragments.

2) the breadth of the claims:

The breadth of the claims is broad and encompasses unspecified variants regarding the tribonectin protein products of SEQ ID NO: 1 as biological active fragments, which are not specifically described or demonstrated in the specification.

Regarding claims 1-6, 28, 29 the specification has listed the alternatively spliced variants of MSF in Table 3, page 10 and also states that a recombinantly or chemically-produced polypeptide containing at least exon 6 (but not exons 1 or 3) of MSF is useful to prevent and/or treat osteoarthritic disease. Furthermore, the specification indicates at page 7 that centrally located exon 6 of MSF gene encodes an O-glycosylated mucin domain and a polypeptide encoded by exon 6 provides boundary lubrication of articular cartilage. However, the specification fails to describe or demonstrate whether these variants from exon 6 are retaining the function of the claimed tribonectin. Thus for these reasons, it requires undue experimentation to make and use the claimed spliced variants.

Claims 16 and 17 are directed to a tribonectin, wherein at least 10% or 40% respectively of said tribonectin is glycosylated. The specification fails to describe a tribonectin, wherein at least 10% or at least 40% of that tribonectin is glycosylated and that demonstrates the desired

activity. The definition of 'glycosylated' at page 4 does not specifically indicate the sites of the peptides where carbohydrate moiety is present. Therefore, it requires undue experimentation to find out those sites on the polypeptide molecule where O-glycosylation would have been found to effectively be a "lubricating moiety".

It is also noted that the specification states that for tribonectins to act as boundary lubricants, the oligosaccharide component of the tribonectin is required (see page 2-4 of the specification). It is not readily apparent whether the tribonectins as claimed comprise the requisite oligosaccharides. Thus, the specification is non-enabling for the broadly claimed tribonectin moieties. The skilled artisan could not make and use the claimed tribonectins without undue experimentation.

The claims 20-27 are directed to a tribonectin comprising a polypeptide that comprises the amino acid sequences which is 50% identical to residues 200-1140, or 200-1167, or 200-1212, or 200-1263, inclusive, of SEQ ID NO: 1 (claims 20, 22, 24, 26); or the amino acid sequences of residues 200-1140, or 200-1167, or 200-1212, or 200-1263, inclusive, of SEQ ID NO: 1 (claims 21, 23, 25, 27). However, the specification fails to provide any description of the structure and function of the fragments claimed. While the specification at page 4 defines the protein or polypeptide fragment as a polypeptide which has an amino acid sequence that is identical to part, but not all, of the amino acid sequence of a naturally-occurring protein or polypeptide from which it is derived, e.g., MSF, however, there is no disclosure about the biological activities of the claimed fragments, wherein the polypeptide still retains the desired properties such that it will function in the manner intended, i.e. in lubricating and/or inhibiting adhesion formation. Given that the claims recite a tribonectin polypeptide having only 50% identity to a polypeptide that provides the desired function, the claims can reasonably be interpreted to encompass polypeptides that do not have the desired properties. However, the specification does not teach which structural elements are required such that the desired functions of the polypeptides are retained. The specification does not disclose or indicate to a polypeptide of the type recited in the claims that is 50% identical to the reference sequence and

retains the desired function. Without any guidance or suggestions a skilled artisan would not be able to predict the structure of a fragment that would demonstrate the same activity as the activity of the full-length protein from where it is derived. Thus, for the reasons set forth above, undue experimentation is required to make and use the claimed fragments.

3) the predictability or unpredictability of the art;

The invention is highly unpredictable for the reasons set forth for factors 1 and 2 above.

As to factors 4 through 6,

4) the amount of direction or guidance presented;

5) the presence or absence of working examples; and,

6) the quantity of experimentation necessary:

The claims are directed to a tribonectin that comprises a polypeptide derived from protein of SEQ ID NO: 1 and spliced variants and fragments thereof; However, the specification provides no description of how these variants and fragments can be generated (page 4), no specific guidance is provided on the generation of the variants or fragments that demonstrate the biological activity of the full length protein from where they are derived. There are no working examples of these variants in the specification. While the specification in pages 21-25, describes and demonstrates the isolation and characterization of tribonectin, there is no disclosure about the biological activities of the claimed variants and fragments. Since the specification fails to provide sufficient guidance on the structure and function of the various spliced variants and fragments, it is necessary to have additional guidance on the identities of variants/fragments to carry out further experimentation to assess their property of lubricating and/or inhibiting adhesion formation.

7) the state of the prior art; and,

8) the relative skill of those skilled in the art:

The prior art has shown fragments of human megakaryocyte stimulating factor (MSF) protein precursor fragments having 98.5% to 100% sequence identity to SEQ ID NO: 1 (see

section below of 102 (b) rejection, however, the general knowledge and level of the skill in the art do not supplement the omitted description. The specification needs to provide specific guidance on the structure and function for various protein products to be considered enabling for variants.

In consideration of each of factors 1-8, it is apparent that there is undue experimentation because in summary, the scope of the claim is broad, the working example does not demonstrate the claimed variants, the guidance/the teaching in the specification is limited, and the outcome is unpredictable for the various modified forms, it is necessary to have additional guidance and to carry out further experimentation to assess the property of the variants/fragments. Therefore, due to large quantity of experimentation necessary to determine an activity or property of the disclosed tribonectins and the modified forms thereof, such that it can be determined how to use the claimed protein, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, the specification fails to teach the skilled artisan how to make and use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-6, 10-13, 16-17, 19-27 and 40-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 are indefinite as to how a peptide structure is modified by an O-linked lubricating moiety (see also the claims dependent to claims 1 and 2).

Claim 10 (and claims dependent thereto) are indefinite since it is not clear what residue(s) are responsible for "reducing the coefficient of friction" or is it the "O-linked lubricating moiety" (which is not a peptide)? See also the "characterized by" terminology, which should be deleted.

Claim 13 is indefinite because of the use of the term "substantially". The term "substantially" renders the claim indefinite because it is not clear what would be that amount of tribonectin, which would not increase the viscosity of a solution.

Claims 16 and 17 (and claims dependent thereto) are ambiguous as to whether or not the glycosylation is or is not the "O-linked lubricating moiety".

Claim 19 is indefinite because of the use of the term "fragment." It is not clear what is the structure of the fragment in relation to the polypeptide sequence and/or in relation to said stimulating factor. It is also not clear whether the said fragment has the same properties of the complete tribonectin protein or megakaryocyte-stimulating factor.

Claims 20, 22, 24, 26 are indefinite because of the use of the term "inclusive". The term "inclusive" renders the claim indefinite, it is not clear whether the sequence identity is to the defined residues or to the complete sequence of SEQ ID NO: 1.

Claims 21, 23, 25, 27 are indefinite because of the use of the term "inclusive". The term "inclusive" renders the claim indefinite, it is not clear whether the polypeptide comprises the sequence of the defined residues or comprises the complete sequence of SEQ ID NO: 1.

Claims 21-26 are indefinite because claim 1 requires exclusion of residues 25-199 but claim 21 would be ", inclusive, of SEQ ID NO: 1" appear to include same.

Claims 40 and 41 are indefinite because it is not clear what is the "form suitable for inhibition of tissue adhesion formation".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Turner et al. (WO 92/13075, 6 August 1992). Turner et al. teach a human megakaryocyte stimulating factor (MSF) protein having 98.5% sequence identity to SEQ ID NO: 1 (see sequence alignment aa1, Clark et al. Feb 2 1993, Database A_Geneseq_1101, Accession NO: AAR26049). Turner et al. and Clark et al. also teach alternatively spliced variants from the sequences encoding MSF protein (see WO'075, page 23, lines 17-30; and entire document of sequence alignment result), thus anticipating claims 1-3 of instant application. Turner et al. and Clark et al.'s sequence is considered for the entire sequence of tribonectin of claim 3 because the claim requires amino acid sequence 1-24 and 200-1404 of SEQ ID NO: 1 (claim 3). Therefore, claims 1-3 of the instant application are being anticipated by Turner et al and Clark et al.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Turner et al. (WO 92/13075, 6 August 1992). Turner et al. teach a human megakaryocyte stimulating factor (MSF) protein having 99.6% sequence identity to SEQ ID NO: 1 (see sequence alignment aa7, Clark et al. Feb 2 1993, Database A_Geneseq_1101, Accession NO: AAR26049). Turner et al. and Clark et al. also teach alternatively spliced variants from the sequences encoding MSF protein (see WO'075, page 23, lines 17-30; and entire document of sequence alignment result), thus anticipating claim 4 of instant application. Turner et al. and Clark et al.'s sequence is considered for the entire sequence of tribonectin of claim 4 because the claim requires amino acid sequence 1-156 and 200-1404 of SEQ ID NO: 1 (claim 4). Therefore, claim 4 of the instant application is being anticipated by Turner et al and Clark et al.

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Turner et al. (WO 92/13075, 6 August 1992). Turner et al. teach a human megakaryocyte stimulating factor (MSF) protein having 99.2% sequence identity to SEQ ID NO: 1 (see sequence alignment aa8, Clark et al. Feb 2 1993, Database A_Geneseq_1101, Accession NO: AAR26049). Turner et al. and Clark et al. also teach alternatively spliced variants from the sequences encoding MSF protein (see WO'075, page 23, lines 17-30; and entire document of sequence alignment result), thus anticipating claim 5 of instant application. Turner et al. and Clark et al.'s sequence is considered for the entire sequence of tribonectin of claim 5 because the claim requires amino acid sequence 1-106 and 200-1404 of SEQ ID NO: 1 (claim 5). Therefore, claim 5 of the instant application is being anticipated by Turner et al and Clark et al.

Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Turner et al. (WO 92/13075, 6 August 1992). Turner et al. teach a human megakaryocyte stimulating factor (MSF) protein having 99.6% sequence identity to SEQ ID NO: 1 (see sequence alignment aa2, Clark et al. Feb 2 1993, Database A_Geneseq_1101, Accession NO: AAR26049). Turner et al. and Clark et al. also teach alternatively spliced variants from the sequences encoding MSF protein (see WO'075, page 23, lines 17-30; and entire document of sequence alignment result), thus anticipating claim 6 of instant application. Turner et al. and Clark et al.'s sequence is considered for the entire sequence of tribonectin of claim 6 because the claim requires amino acid sequence 1-25 and 67-1404 of SEQ ID NO: 1 (see sequence alignment aa2) and also 1-25, 67-106 and 200-1404 of SEQ ID NO: 1 (see sequence alignment aa3). Therefore, claim 6 of the instant application is being anticipated by Turner et al and Clark et al.

Claims 1, 19, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Turner et al. (WO 92/13075, 6 August 1992). Turner et al. teach a human megakaryocyte stimulating factor (MSF) protein having 100% sequence identity to residues 200-1140 of SEQ ID NO: 1 (see sequence alignment, Clark et al. Feb 2 1993, Database A_Geneseq_1101, Accession NO: AAR26049). Turner et al. and Clark et al. also teach an analog of amino acid sequences of MSF protein (see WO'075, page 19, lines 26-35; and entire document of sequence

alignment result), thus anticipating claims 19, 20 and 21 of instant application. Turner et al. and Clark et al.'s sequence is considered for a fragment of MSF (claim 19) and for a fragment of SEQ ID NO: 1 that includes residues 200-1140 of SEQ ID NO: 1 (claims 20, 21). Therefore, claims 19-21 of the instant application is being anticipated by Turner et al and Clark et al.

Claims 1, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Turner et al. (WO 92/13075, 6 August 1992). Turner et al. teach a human megakaryocyte stimulating factor (MSF) protein having 100% sequence identity to residues 200-1167 of SEQ ID NO: 1 (see sequence alignment, Clark et al. Feb 2 1993, Database A_Geneseq_1101, Accession NO: AAR26049). Turner et al. and Clark et al. also teach an analog of amino acid sequences of MSF protein (see WO'075, page 19, lines 26-35; and entire document of sequence alignment result), thus anticipating claims 22 and 23 of instant application. Turner et al. and Clark et al.'s sequence is considered for a fragment of SEQ ID NO: 1 that includes residues 200-1167 of SEQ ID NO: 1 (claims 22, 23). Therefore, claims 22 and 23 of the instant application is being anticipated by Turner et al and Clark et al.

Claims 1, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Turner et al. (WO 92/13075, 6 August 1992). Turner et al. teach a human megakaryocyte stimulating factor (MSF) protein having 100% sequence identity to residues 200-1212 of SEQ ID NO: 1 (see sequence alignment, Clark et al. Feb 2 1993, Database A_Geneseq_1101, Accession NO: AAR26049). Turner et al. and Clark et al. also teach an analog of amino acid sequences of MSF protein (see WO'075, page 19, lines 26-35; and entire document of sequence alignment result), thus anticipating claims 24 and 25 of instant application. Turner et al. and Clark et al.'s sequence is considered for a fragment of SEQ ID NO: 1 that includes residues 200-1212 of SEQ ID NO: 1 (claims 24, 25). Therefore, claims 24 and 25 of the instant application is being anticipated by Turner et al and Clark et al.

Claims 1, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Turner et al. (WO 92/13075, 6 August 1992). Turner et al. teach a human megakaryocyte stimulating factor (MSF) protein having 100% sequence identity to residues 200-1263 of SEQ ID NO: 1 (see

sequence alignment, Clark et al. Feb 2 1993, Database A_Geneseq_1101, Accession NO: AAR26049). Turner et al. and Clark et al. also teach an analog of amino acid sequences of MSF protein (see WO'075, page 19, lines 26-35; and entire document of sequence alignment result), thus anticipating claims 26 and 27 of instant application. Turner et al. and Clark et al.'s sequence is considered for a fragment of SEQ ID NO: 1 that includes residues 200-1263 of SEQ ID NO: 1 (claims 26, 27). Therefore, claims 26 and 27 of the instant application is being anticipated by Turner et al and Clark et al.

Claims 1 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Turner et al. (WO 92/13075, 6 August 1992). Turner et al. teach a human megakaryocyte stimulating factor (MSF) protein having 100% sequence identity to residues 25-1404 of SEQ ID NO: 1 (see sequence alignment, Clark et al. Feb 2 1993, Database A_Geneseq_1101, Accession NO: AAR26049). Turner et al. and Clark et al. also teach an analog of amino acid sequences of MSF protein (see WO'075, page 19, lines 26-35; and entire document of sequence alignment result), thus anticipating claim 28 of instant application. Turner et al. and Clark et al.'s sequence is considered for a fragment of SEQ ID NO: 1 that includes residues 25-1404 of SEQ ID NO: 1 (claim 28). Therefore, claim 28 of the instant application is being anticipated by Turner et al and Clark et al.

Claims 1 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Turner et al. (WO 92/13075, 6 August 1992). Turner et al. teach a human megakaryocyte stimulating factor (MSF) protein having 99.6% sequence identity to SEQ ID NO: 1 (see sequence alignment aa6, Clark et al. Feb 2 1993, Database A_Geneseq_1101, Accession NO: AAR26049). Turner et al. and Clark et al. also teach alternatively spliced variants from the sequences encoding MSF protein (see WO'075, page 23, lines 17-30; and entire document of sequence alignment result), thus anticipating claim 29 of instant application. Turner et al. and Clark et al.'s sequence is considered for the entire sequence of tribonectin of claim 29 because the claim requires amino acid sequence 1-66 and 105-1404 of SEQ ID NO: 1 (see sequence alignment aa6). Therefore, claim 29 of the instant application is being anticipated by Turner et al and Clark et al.

Claims 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Turner et al. (WO 92/13075, 6 August 1992). Turner et al. teach a purification and biochemical characterization of human megakaryocyte stimulating factor (MSF), see Example 1, page 37. The purified homogeneous protein obtained, having a specific activity ranging from about $5x10^7$ to $2\text{-}5x10^8$ dilution units per mg protein (see page 40, lines 2-6). Therefore the protein is in a buffer or in water, thus anticipates the composition of claim 40 of the instant application.

Conclusion

No claim is allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr.Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Christopher S. F. Low

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SUPERVISORY PATENT EXAMINER
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R Mitra

Rita Mitra, Ph.D.
May 16, 2002